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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,587	01/31/2002	Harvey D. Preisler	047940-0135	1948

23524 7590 10/12/2005

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/062,587	PREISLER, HARVEY D.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,3-21,33 and 55-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *1,3-21 and 33* is/are allowed.

6)☐ Claim(s) *55-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 25, 2005 has been entered.

Claims 22-32 and 34-54 have been canceled. Claims 55-84 have been added. Claims 1, 3-21, 33 and 55-84 are pending and under consideration.

Sections of Title 35, U.S. Code not found in this action can be found in a prior action.

Claims 55-62, 69, 73-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. .

The instant claims are drawn to isolated polypeptides which minimally comprise SEQ ID NO:1-23 and 36-31 having one conservative amino acid substitution. Claims 56-58 specify that the substitution is at a hydrophobic residue; and claims 59-62 specify the substitution is at a polar residue. Claim 69 embodies the polypeptide of claim 55 comprising SEQ ID NO:1-6, 15, 19, 21 and 22 having one conservative amino acid substitution, wherein said polypeptide binds to both malignant and non-malignant myeloid cells. The claims are thus drawn to a genus of polypeptides which minimally comprise a structural variant of SEQ ID NO:1-23 and 26-31. It is noted that SEQ ID NO:1-23 and 26-31 range in length from 8 to 10 amino acids. A single alteration of amino acid would be equivalent to a 10% to 12.5% difference. Further, the claim does not restrict the amino acid substitution to a specific residue, this all positions are subject to the conservative amino acid alteration. The claims are not limited by a recitation of the functional attribute of the variant polypeptide. The limitation of binding to malignant and non-malignant myeloid cells does not narrow the genus appropriately because "myeloid" cells

encompass a large genus of cell types, which carry different cell surface proteins. Thus, polypeptides which bound to completely different structures on said myeloid than the disclosed SEQ ID NO:1-23 and 26-31 would be permitted within the claimed genus. Overall, the claims encompass a genus of proteins which are highly variant in both structure and function. The disclosure of SEQ ID NO:1-23 and 26-31 does not adequately describe the claimed genus because the genus encompasses polypeptides which differ significantly in structure and function from SEQ ID NO:1-23 and 26-31. One of skill in the art would conclude that applicant was not in possession of the claimed genus.

Claims 63-68, and 70-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention..

Claim 63 embodies the isolated polypeptide of claim 55 selected from SEQ ID NO: 1-3, 15, 16 and 22 having one conservative amino acid substitution, wherein the polypeptide binds to CML or AML but not to normal bone marrow cells, CD+34 cells or blood cells. Claim 64 embodies the polypeptide of claim 55 comprising SEQ ID NO:3 having one conservative amino acid substitution, wherein the polypeptide binds to CML, AML and blood cells. Claim 65 embodies the polypeptide of claim 55 comprising SEQ ID NO:1 or 2 having one conservative amino acid substitution, wherein the polypeptide binds to CML and AML but not to cord blood ells. Claim 66 embodies the polypeptide of claim 55 comprising SEQ ID NO:22 having one conservative amino acid substitution, wherein the polypeptide binds to CML, AML and cord blood. Claim 68 embodies the polypeptide of claim 55 comprising SEQ ID NO: 1 or 4 having one conservative amino acid substitution, wherein the polypeptide binds to CLL but not normal peripheral blood cells. Claim 70 embodies the polypeptide of claim 55 comprising SEQ ID NO:1-3, 5, 6, 19, 21 and 22 having one conservative amino acid substitution, wherein the polypeptide binds to CLL and normal peripheral blood. Claim 71 embodies the polypeptide of claim 55 comprising SEQ ID NO:1-4, 15, 19 or 22 having one conservative amino acid substitution, wherein the polypeptide binds CML, AML but not to CLL. Claim 72 embodies the

polypeptide of claim 55 comprising SEQ ID NO:1-6, 19, 21 or 22 having one conservative amino acid substitution, wherein the polypeptide binds to CML, AML and CLL.
The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re wands, 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

One of skill in the art would be subject to undue experimentation in order to make and use said polypeptides because of the conflicted data presented in the specification about characteritics of the claimed polypeptides having the same sequence. For instance in paragraph [0145] the specification states that SEQ ID NO:1 binds to CML and AML, paragraph [0151] states that SEQ ID NO:1 binds to CLL. However, paragraph [0152] states that SEQ ID NO:1 does not bind to CLL. The same logic can be applied to SEQ ID NO:2, 3, 4, 19 and 22. the specification fails to teach what part of the clone comprising the polypeptide is influencing the binding specificity of the displayed polypeptide. Because it is unknown how the same displayed polypeptide can vary in binding specificity, one of skill in the are would be subject to undue experimentation in order to make the claimed conservatively substituted variants with the required binding specificity as recited in claims 63-68, and 70-72.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
10/3/2005

KAREN A. CANELLA PH.D
PRIMARY EXAMINER

Karen A Canella

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